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EXAMINER
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ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/428,036	NEWTON ET AL.
	Examiner	Art Unit
	Robert W. Morgan	3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. In the amendment filed 3/1/03 in paper number 9, the following has occurred: Claims 28-45 has been added. Now claims 1-45 are presented for examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 10-14, 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,502,944 to Kraft et al.

As per claim 1, Kraft et al. teaches method comprising the step of:

(a) the claim storing in at least one data store in operative connection with at least one computer, data representative of at least one patient and at least one medical item prescribed for use by the patient is met by storing information concerning a patient's medication requirements on the pharmacy system (14, Fig. 1) (see: column 4, lines 56-59);

(b) the claimed storing in the data store, data representative of a plurality of holding locations for medical items in a medical item dispenser, a plurality of types of medical items, and for each of the storage locations, a type medical item stored in the respective storage location is met by the pharmacy computer system that maintains a database of the medication, the manufacturer, the brand name, the generic name, the dosage form, the location of the drug in the pharmacy, and pricing information (see: column 1, lines 29-34);

(c) the claimed inputting through an input device in operative connection with the computer and the dispenser, data corresponding to the patient is met by keyboard (28, Fig. 2);

(d) the claimed dispensing from the responsive to the data stored in the data store, the type medical item prescribed for use by the patient, wherein the type medical item in dispensed from a storage location holding the type medical item in the dispenser is met by the dispensing process where the nurse enter commands through the system controller (34, Fig. 3) to retrieve medication for one or more patients (see: column 4, lines 54-56);

(e) the claimed including in the data store responsive to execution of step (d), data representative that the type medical item has been dispensed for use by the patient, and that the type medical item has been dispensed from the dispenser is met once the nurse orders all or part of the authorized medication for each of the nurse's patients for a given medication round, the medication dispenser (12, Fig. 1) retrieves each medication from its respective container and dispenses the medication (see: column 4, lines 60-65).

As per claim 10, Kraft et al. teaches the claimed step (d) further comprising the step of displaying on an output device adjacent to the dispenser, display indicia including

indicia indicative of the type medical item. This feature is met by the video display (26, Fig. 2) and printer (30, Fig. 2) connected to the medication dispenser (see: column 4, lines 3-15 and Fig. 2).

As per claim 11, Kraft et al. teaches prior to step (d) further comprising the step of receiving an input through an input device indicating agreement with the display indicia. The dispensing process meets this feature where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2) connected to the medication dispenser (see: column 4, lines 54-56).

As per claim 12, Kraft et al. teaches prior to step (a), inputting through a physician terminal in operative connection with the computer, prescription data representative of information that the medical item has been prescribed for the patient, and a medical condition for which the medical item has been prescribed, wherein in step (a) the data stored includes prescription data, and wherein in the displaying step the display indicia includes indicia indicative of the medical condition. The dispensing process meets this limitation where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2) and video display (26, Fig. 2) connected to the medication dispenser (see: column 4, lines 54-56). The information concerning the patient medication requirement is stored in the pharmacy system (14, Fig. 1) and when the medication package given to the patient include a label with information such as patient's name, room number, doctor's name and other data as required (see: column 4, lines 60 to column 5, lines 2).

As per claims 13-14, Kraft et al. teaches a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2),

video display (26, Fig. 2) and printer (30, Fig. 2) all connected to the medication dispenser (see: column 4, lines 54-56). The information concerning the patient medication requirement is stored in the pharmacy system (14, Fig. 1) and when the medication package given to the patient include a label with information such as patient's name, room number, doctor's name and other data as required (see: column 4, lines 60 to column 5, lines 2).

As per claim 26, Kraft et al. teaches a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2), video display (26, Fig. 2) and printer (30, Fig. 2) all connected to the medication dispenser (see: column 4, lines 54-56). The information concerning the patient medication requirement is stored in the pharmacy system (14, Fig. 1) and when the medication package given to the patient include a label with information such as patient's name, room number, doctor's name and other data as required (see: column 4, lines 60 to column 5, lines 2). Kraft et al. further teaches a vision subsystem (44, Fig. 4) that interacts with the medication unit from a selected container to the medication package subsystem (38, Fig. 3) (see: column 6, lines 35-37). In addition, the vision subsystem (44, Fig. 4) comprises two optic systems for comparing specific medication in order to verify that the correct medication is being dispensed (see: column 7, lines 26-34). The Examiner considers the comparison for dispensing purposes to include checking data representative of a medical history of the patient corresponding to inputted patient data.

As per claim 27, Kraft et al. teaches a plurality of medication dispenser (12, Fig. 1) coupled to a pharmacy computer system (14, Fig. 1) and to each other through a network (16, Fig. 1) (Internet) (see: column 52-55). In addition, the vision subsystem (44,

Fig. 4) compares specific medication in order to verify that the correct medication is being dispensed (see: column 7, lines 26-34). The Examiner considers the comparison for dispensing purposes to include checking data representative of a medical history of the patient corresponding to inputted patient data.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2, 9 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,502,944 to Kraft et al. in view U.S. Patent No. 5,797,515 to Liff et al.

As per claim 2, Kraft et al. teaches a medication dispensing system that storing information concerning a patient's medication requirements on the pharmacy system (14, Fig. 1) (see: column 4, lines 56-59). Kraft et al. further teaches a pharmacy computer system (14, Fig. 1) which maintains a database of the medication, the manufacturer, the brand name, the generic name, the dosage form, the location of the drug in the pharmacy, and pricing information (see: column 1, lines 29-34). In addition, Kraft et al. teach a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) to retrieve medication for one or more patients (see: column 4, lines 54-56).

Kraft et al. fails to teach data representative of a benefit plan associated with the patient, and payment rules concerning payment for medical items associated with the

benefit plan and further comprising the step of charging for the dispensed medical item in accordance with the payment rules.

Liff et al. teaches a drug dispensing system that uses an electronic third-party payor card for drug purchases at the doctor's office (see: column 4, lines 67 to column 5, lines 2). Liff et al. also teaches that during the claim adjudication step (286, Fig. 12) a patient's insurance information is automatically verified to determine whether the insurer will pay for the prescription and if any co-payment is required (see: column 13, lines 12-42 and column 16, lines 40-52). The Examiner considers the step of verifying insurance and payment information a form of evaluating the rules and regulation associated with making a payment for a prescription.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the drug dispensing system as taught by Liff et al. within the medication dispensing system as taught by Kraft et al. with the motivation of having a patient's insurance information readily available at the physician's office, thereby avoiding the inconvenience of taking a trip the pharmacy (see: Liff et al.: column 4, lines 62-64).

As per claim 9, Kraft et al. teaches a medication dispensing system that storing information concerning a patient's medication requirements on the pharmacy system (14, Fig. 1) (see: column 4, lines 56-59). Kraft et al. further teaches a pharmacy computer system (14, Fig. 1) which maintains a database of the medication, the manufacturer, the brand name, the generic name, the dosage form, the location of the drug in the pharmacy, and pricing information (see: column 1, lines 29-34). In addition, Kraft et al. teaches a dispensing process where the nurse enters commands through the system controller (34,

Fig. 3) using a keyboard (28, Fig. 2) to retrieve medication for one or more patients (see: column 4, lines 54-56).

Kraft et al. fails to teach storing and inputting data representative of a benefit plan associated with the patient. Kraft et al. also fails to teach charging for the medical item in accordance with the payment rules associated with the benefit plan determined to be associated with the patient.

Liff et al. teaches a host computer (46, Fig. 1) using pharmacy software packages that provide standard administrative and accounting capabilities and support features of the dispensing system such as a document printer (60, Fig. 1), that generates documents containing instruction for the patient or the practitioner and a keyboard (50, Fig. 1) that inputs the commands of the user (see: column 5, lines 19-25, 58-63 and column 7, lines 24-37). Liff et al. also teaches during the claim adjudication step (286, Fig. 12) a patient's insurance information is automatically verified to determine whether the insurer will pay for the prescription and if any co-payment is required (see: column 13, lines 12-42, column 16, lines 40-52 and Fig. 1).

The motivation for combining the teaching of Kraft et al. and Liff et al. are discussed in the rejection of claim 2, and are incorporated herein.

As per claim 15, Liff et al. teaches a document printer that prints instructions specific to a dispensed pharmaceutical for use by the patient or medical practitioner (see: column 2, lines 58-67).

As per claim 16, Kraft et al. teaches a medication dispensing system that storing information concerning a patient's medication requirements on the pharmacy system (14, Fig. 1) (see: column 4, lines 56-59). Kraft et al. further teaches a dispensing process

where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2), video display (26, Fig. 2) and printer (30, Fig. 2) all connected to the medication dispenser (see: column 4, lines 54-56). The information concerning the patient medication requirement is stored in the pharmacy system (14, Fig. 1) and when the medication package given to the patient include a label with information such as patient's name, room number, doctor's name and other data as required (see: column 4, lines 60 to column 5, lines 2). In addition, Kraft et al. teaches a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2) to retrieve medication for one or more patients (see: column 4, lines 54-56).

As per claims 17 and 18, Liff et al. teaches the step of applying to the type medical item, indicia indicative of data included in the prescription data and prescription data including instruction for using the type medical item and the medical item includes indicia indicative of the instruction (see: column 5, lines 58-63).

As per claim 19, Liff et al. teaches the step of printing a prescription label, wherein the prescription label includes the indicia indicative of the data included in the prescription data, wherein in the applying step the label is applied in connection with the type medical item (see: column 5, lines 58-63).

As per claims 20 and 21, Kraft et al. teaches applying the step of executing the prior to step (d), wherein the indicia indicative of data included in prescription data is applied to the type medical item to be dispensed in step (d). This feature is met by each medication package for a given patient are labeled with information including patient's name, room number, doctor's name and other data as required (see: column 4, lines 60 to column 5, lines 2).

As per claim 22, Liff et al. teaches a label printer coupled to the controller for printing a patient prescription label for attaching to a dispensed pharmaceutical package. The label printer is inhibited until the bar-code reader verifies that the proper dispensing of the pharmaceutical has occurred (see: column 2, lines 53-67).

As per claim 23, Kraft et al. and Liff et al. teaches a medication dispensing system that storing information concerning a patient's medication requirements on the pharmacy system (14, Fig. 1) (see: column 4, lines 56-59). Kraft et al. further teaches a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2), video display (26, Fig. 2) and printer (30, Fig. 2) all connected to the medication dispenser (see: Kraft et al.: column 4, lines 54-56). The information concerning the patient medication requirement is stored in the pharmacy system (14, Fig. 1) and when the medication package given to the patient include a label with information such as patient's name, room number, doctor's name and other data as required (see: Kraft et al.: column 4, lines 60 to column 5, lines 2). In addition, Kraft et al. teaches a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2) to retrieve medication for one or more patients (see: Kraft et al.: column 4, lines 54-56). Additionally, Kraft et al. and Liff et al. teaches that a licensed user, for example, a doctor, pharmacist, nurse, or other medical practitioner using a keyboard (50, Fig. 1) enters a command to request dispensing of a particular package pharmaceutical variety (32, Fig. 1) for a particular patient (see: Liff et al. column 5, lines 19-25).

6. Claims 3-8, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,502,944 to Kraft et al. in view U.S. Patent No. 5,797,515 to Liff et al. in further view of Official Notice.

As per claim 3, Kraft et al. and Liff et al. teaches a card reader (38, Fig. 1) mounted directly to or near the cabinet and connected to the host computer (46, Fig. 1), where the patient inserts a card (39, Fig. 1) in the card reader (38, Fig. 1) to automatically receive medicine from the cabinet (see: Liff et al.: column 5 lines 47-53 and Fig. 1).

Kraft et al. and Liff et al. fail to teach a reading a credit or debit card with a card reading device adjacent the dispenser, wherein the card reading device is in operative connection with the computer, and the charging step includes charging an account associated with the credit or debit card.

The Examiner takes Official Notice that, in the medical industry, the use of cash, checks or credit cards are old and well-known methods of payment for patient health care. One of ordinary skill in the art would have found it obvious at the time the invention was made to include the charging of a customer's credit or debit card with the system as taught by the Kraft et al. and Liff et al. with the motivation of providing a fast and beneficial way for customers to make purchase and payment for prescription medicine.

As per claims 4-6, Kraft et al. and Liff et al. et al. teaches a drug dispensing system that uses an electronic third-party payor card for drug purchases at the doctor's office (see: Liff et al. column 4, lines 67 to column 5, lines 2). Kraft et al. and Liff et al. also teaches that during the claim adjudication step (286, Fig. 12) a patient's insurance information is automatically verified to determine whether the insurer will pay for the

prescription and if any co-payment is required (see: Liff et al. column 13, lines 12-42 and column 16, lines 40-52).

Kraft et al. and Liff et al. fail to explicitly teach a charging step of charging the benefits provider, charging the co-pay amount and charging the benefits provider the benefit amount. The Examiner takes Official Notice that, in the medical industry cash, checks or credit cards are old and well-known methods of payment for patient health care, for instance, a patient may have to pay a deductible to be seen by a their physician usually about $10-15 dollars with a credit card and the patient's medical insurance company would pay for the remaining amount.

The motivation for combining the teaching of Kraft et al. and Liff et al. are discussed in the rejection of claim 3, and are incorporated herein.

As per claims 7 and 8, Kraft et al. and Liff et al. fail to explicitly teach inputting and outputting information representative of the co-payment amount and acceptance of the co-pay amount.

However, Kraft et al. and Liff et al. teach a host computer (46, Fig. 1) using pharmacy software packages that provide standard administrative and accounting capabilities and support features of the dispensing system such as a document printer (60, Fig. 1), that generates documents containing instruction for the patient or the practitioner and a keyboard (50, Fig. 1) that inputs the commands of the user (see: Liff et al. column 5, lines 19-25, 58-63 and column 7, lines 24-37). Kraft et al. and Liff et al. also teach during the claim adjudication step (286, Fig. 12) a patient's insurance information is automatically verified to determine whether the insurer will pay for the prescription and

if any co-payment is required (see: Liff et al. column 13, lines 12-42, column 16, lines 40-52 and Fig. 1).

The motivation for combining the teaching of Kraft et al. and Liff et al. are discussed in the rejection of claim 3, and are incorporated herein.

As per claim 24, Kraft et al. and Liff et al. teaches a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2) to retrieve medication for one or more patients (see: Kraft et al.: column 4, lines 54-56). Kraft et al. and Liff et al. also teaches that a licensed user, for example, a doctor, pharmacist, nurse, or other medical practitioner using a keyboard (50, Fig. 1) enters a command to request dispensing of a particular package pharmaceutical variety (32, Fig. 1) for a particular patient (see: Liff et al. column 5, lines 19-25).

Kraft et al. and Liff et al. fail to teach contacting the patient corresponding to the data inputted in step (c) after failing to executing step (d).

The Examiner takes Official Notice that it is common in the medical field, for a patient or a physician to be contacted if the pharmacist in order to clarify any discrepancies or make any modification to the prescription does not verify prescription information. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method of contacting a patient to verify information with the system as taught by Kraft et al. and Liff et al. with the motivation of gathering accurate and reliable patient information thereby ensuring that the patient receives the correct prescription.

As per claim 25, Kraft et al. and Liff et al. teaches a medication dispensing system that storing information concerning a patient's medication requirements on the pharmacy

system (14, Fig. 1) (see: Kraft et al.: column 4, lines 56-59). Kraft et al. further teaches a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2), video display (26, Fig. 2) and printer (30, Fig. 2) all connected to the medication dispenser (see: Kraft et al.: column 4, lines 54-56). The information concerning the patient medication requirement is stored in the pharmacy system (14, Fig. 1) and when the medication package given to the patient include a label with information such as patient's name, room number, doctor's name and other data as required (see: Kraft et al.: column 4, lines 60 to column 5, lines 2).

Kraft et al. and Liff et al. fail to explicitly teach contacting the physician responsive to the failing of step (d).

The Examiner takes Official Notice that it is common in the medical field, for a patient or a physician to be contacted if the pharmacist in order to clarify any discrepancies or make any modification to the prescription does not verify prescription information. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method of contacting a patient to verify information with the system as taught by Kraft et al. and Liff et al. with the motivation of gathering accurate and reliable patient information thereby ensuring that the patient receives the correct prescription.

7. Claims 28-31, 34-37, 39 and 42-~~45~~ 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,502,944 to Kraft et al. in view U.S. Patent No. 5,036,416 to Kaufman et al.

As per claim 28, Kraft teaches a dispensing process where the nurse enters commands through the system controller (34, Fig. 3) to retrieve medication for one or more patients (see: column 4, lines 54-56).

Kraft et al. fails to teach a dispenser comprises a patient accessible self-service medical item dispenser.

Kaufman et al. teaches an interactive patient assistance and delivery system that includes a system (200, Fig. 11) for storing and delivering of individual pills or caplets as well as both external and internal devices (55, Fig. 5) for receiving input from the physician (or healthcare professional at the central monitoring facility 28, Fig. 4a), the individual patient, the physical testing devices (34, Fig. 4a) and (36, Fig. 4a) and the environmental sensors (23, Fig. 8a) and (25, Fig. 8a) in order to gain access to the medication delivery system (20, Fig. 5) (see: column 8, lines 15-23, column 17, lines 1-22 and Fig. 11-13).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include receiving patient input to gain access the medication delivery system as taught by Kaufman et al. within the medication dispensing system as taught by Kraft et al. with the motivation of providing a system with a reasonable degree of self-sufficiency and personal control over the administration of medication without sacrificing the overall therapeutic objectives of the prescribed medical treatment (see: Kaufman et al.: column 2, lines 4-7).

As per claim 29, Kaufman et al. teaches prior to (d), receiving input from a patient through at least one input device in operative connection with the computer and the dispenser. This limitation is met by the system (20, Fig. 5) including various external

input devices that receive commands from the patient, which are communicated to the control element (50, Fig. 5) through the main CPU (22, Fig. 4) for the administering of medication "upon demand" (see: column 8, lines 30-37).

As per claim 30, Kaufman et al. teaches (f) includes receiving dispense request input from the patient corresponding to at least one medical item prescribed for use by the patient. This feature is met by the system (20, Fig. 5) including various external input devices that receive commands from the patient, which are communicated to the control element (50, Fig. 5) through the main CPU (22, Fig. 4) for the administering of medication "upon demand" (see: column 8, lines 30-37). In addition, the medication control element (50, Fig. 5) can store and selectively administer medication upon demand by patient (see: column 9, lines 17-25).

As per claim 31, Kraft et al. teaches receiving a payment from the patient corresponding to the at least one medical item requested in the dispense request input. This limitation is met by the plurality of dispensers that are networked together and connected to a common database of patient information, typically a pharmacy software system. Medications are automatically dispensed responsive to a user request in accordance with the information in the database and the dispensers communicates data for accounting and billing purposes, to the pharmacy system or to another system (see: column 2, lines 22-29).

As per claim 34, Kraft et al. teaches storing information concerning a patient's medication requirements on the pharmacy system (14, Fig. 1) (see: column 4, lines 56-59). Kraft et al. further teaches that during the dispensing process a nurse using a keyboard (28, Fig. 2) enters commands through the system controller (34, Fig. 3) for

orders of all or part of the authorized medication for each of the nurse's patients for a given medication round and the medication dispenser (12, Fig. 1) retrieves each medication from its respective container and dispenses the medication (see: column 4, lines 54-65). In addition, Kraft et al. teaches that the system controller (34, Fig. 3) communicates accounting information for bill purposes as the medication is dispensed and the information concerning the quantity and type of medication dispensed for each is patient is communicated to the pharmacy system (see: column 5, lines 47-55). Moreover, Kraft et al teaches a vision subsystem (44, Fig. 4) comprises two optic systems for comparing specific medication in order to verify that the correct medication is being dispensed (see: column 7, lines 26-34).

Kraft et al. fails to teach:

(a) at least one medical item stored in a patient-accessible self service medical item dispenser apparatus, wherein the dispenser apparatus is operative to receive at least one input from the at least one patient;

(c) responsive to the request to dispense, instructing the dispenser apparatus to dispense the requested at least one medical item to the first patient;

Kaufman et al. teaches an interactive patient assistance and delivery system that includes a system (200, Fig. 11) for storing and delivering of individual pills or caplets as well as both external and internal devices (55, Fig. 5) for receiving input from the physician (or healthcare professional at the central monitoring facility 28, Fig. 4a), the individual patient, the physical testing devices (34, Fig. 4a) and (36, Fig. 4a) and the environmental sensors (23, Fig. 8a) and (25, Fig. 8a) in order to gain access to the

medication delivery system (20, Fig. 5) (see: column 8, lines 15-23, column 17, lines 1-22 and Fig. 11-13).

The obviousness of combining the teachings of Kaufman et al. within the system as taught by Kraft et al. is discussed in the rejection of claim 28, and incorporated herein.

As per claim 35, Kraft et al. teaches the claimed responsive to the verification, including in the data store, data linking each of the first patient, the dispensed at least one medical item, and location of dispensing the at least one medical item. This limitation is met during the dispensing process when a nurse using a keyboard (28, Fig. 2) enters commands through the system controller (34, Fig. 3) for orders of all or part of the authorized medication for each of the nurse's patients for a given medication round and the medication dispenser (12, Fig. 1) retrieves each medication from its respective container and dispenses the medication (see: column 4, lines 54-65). In addition, Kraft et al. teaches that the system controller (34, Fig. 3) communicates accounting information for bill purposes as the medication is dispensed and the information concerning the quantity and type of medication dispensed for each is patient is communicated to the pharmacy system (see: column 5, lines 47-55). Moreover, Kraft et al teaches a vision subsystem (44, Fig. 4) comprises two optic systems for comparing specific medication in order to verify that the correct medication is being dispensed (see: column 7, lines 26-34). The Examiner considers the nurse to be entering information regarding multiple patient and the dispensed medication could be for one or more patient.

As per claim 36, Kraft et al. teaches (f) receiving another at least one input through the at least one input device of the dispenser apparatus, wherein the another at

least one input includes a request to dispense to a second patient at least one medical item prescribed for use by the second patient; and

(g) responsive to the request to dispense to the second patient, instructing the dispenser apparatus to dispense the requested at least one medical item to the second patient. These limitations are met during the dispensing process a nurse using a keyboard (28, Fig. 2) enter commands through the system controller (34, Fig. 3) to retrieve medication for one or more patients (reads on "request to dispense to a second patient") (see: column 4, lines 54-56).

Kraft et al. fails to teach dispensing to the patient.

Kaufman et al. teaches an interactive patient assistance and delivery system that includes a system (200, Fig. 11) for storing and delivering of individual pills or caplets as well as both external and internal devices (55, Fig. 5) for receiving input from the physician (or healthcare professional at the central monitoring facility 28, Fig. 4a), the individual patient, the physical testing devices (34, Fig. 4a) and (36, Fig. 4a) and the environmental sensors (23, Fig. 8a) and (25, Fig. 8a) in order to gain access to the medication delivery system (20, Fig. 5) (see: column 8, lines 15-23, column 17, lines 1-22 and Fig. 11-13).

The obviousness of combining the teachings of Kaufman et al. within the system as taught by Kraft et al. is discussed in the rejection of claim 28, and incorporated herein.

As per claim 37, Kraft et al. teaches storing information concerning a patient's medication requirements on the pharmacy system (14, Fig. 1) (see: column 4, lines 56-59). Kraft et al. further teaches that during the dispensing process a nurse using a keyboard (28, Fig. 2) enters commands through the system controller (34, Fig. 3) for

orders of all or part of the authorized medication for each of the nurse's patients for a given medication round and the medication dispenser (12, Fig. 1) retrieves each medication from its respective container and dispenses the medication (see: column 4, lines 54-65). In addition, Kraft et al. teaches that the system controller (34, Fig. 3) communicates accounting information for bill purposes as the medication is dispensed and the information concerning the quantity and type of medication dispensed for each is patient is communicated to the pharmacy system (see: column 5, lines 47-55).

Kraft et al. fails to teach:

wherein (b) includes receiving dispense request input from the first patient through an input device in operative connection with the first dispenser, and further comprising

receiving dispense request input from the second patient through an input device in operative connection with the second dispenser;

responsive to (f), instructing the second dispenser to dispense to the second patient at least one medical item prescribed for use by the second patient.

Kaufman et al. teaches an interactive patient assistance and delivery system that includes a system (200, Fig. 11) for storing and delivering of individual pills or caplets as well as both external and internal devices (55, Fig. 5) for receiving input from the physician (or healthcare professional at the central monitoring facility 28, Fig. 4a), the individual patient, the physical testing devices (34, Fig. 4a) and (36, Fig. 4a) and the environmental sensors (23, Fig. 8a) and (25, Fig. 8a) in order to gain access to the medication delivery system (20, Fig. 5) (see: column 8, lines 15-23, column 17, lines 1-22 and Fig. 11-13).

The obviousness of combining the teachings of Kaufman et al. within the system as taught by Kraft et al. is discussed in the rejection of claim 28, and incorporated herein.

As per claim 38, Kraft et al teaches (f) prior to (c), receiving with the dispenser apparatus a patient payment input. This limitation is met during the dispensing process a nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2), video display (26, Fig. 2) and printer (30, Fig. 2) all connected to the medication dispenser (see: column 4, lines 54-56). In addition, Kraft et al. teaches that a system controller (34, Fig. 3) communicates accounting information for the bill purposes of the patient as the medication is dispensed and the information concerning the quantity and type of medication dispensed for each is patient is communicated to the pharmacy system (see: column 5, lines 47-55). The Examiner considers the video display connected to the dispenser capable of including the accounting information such as patient payment information before the information is communicated to the pharmacy system.

As per claim 39, it is rejected for the same reasons set forth in claim 31.

As per claim 42, Kraft et al. teaches (g) prior to (c), displaying a payment amount to the patient with the display screen. This feature is met during the dispensing process when a nurse enters commands through the system controller (34, Fig. 3) using a keyboard (28, Fig. 2), video display (26, Fig. 2) and printer (30, Fig. 2) all connected to the medication dispenser (see: column 4, lines 54-56). In addition, Kraft et al. teaches that a system controller (34, Fig. 3) communicates accounting information for the bill purposes of the patient as the medication is dispensed and the information concerning the quantity and type of medication dispensed for each is patient is communicated to the pharmacy system (see: column 5, lines 47-55). The Examiner considers the video display

connected to the dispenser capable of including the accounting information such as patient payment information before the information is communicated to the pharmacy system.

As per claim 43, Kraft teaches the claimed prior to (c), determining whether the at least one medical item corresponding to the dispense request input is available for dispensing from the dispenser apparatus. This limitation is met by the control electronics (36, Fig. 3) that maintains a database of information concerning the contents of the dispenser. In response to a request, the control electronics (36, Fig. 3) determines whether all requested medications are available (see: column 6, lines 19-22).

As per claim 44, Kraft et al. teaches the claimed (d) further comprises at least one sensor in the dispenser apparatus transmitting at least one signal responsive to the at least one sensor sensing a passing of the requested at least one medical item, and (e) further comprises including in the data store verification of the dispensing of the at least one medical item. This limitation is met by the detector (340, Fig. 24) that outputs a signal indicating whether a pill from a container (130, Fig. 8) has landed in the package (see: column 12, lines 58-66).

8. Claims 32-33, 40-41 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,502,944 to Kraft et al. and U.S. Patent No. 5,036,416 to Kaufman et al. in view of U.S. Patent No. 5,301,105 to Cummings, Jr.

As per claim 32, Kraft et al. and Kaufman et al. teach system (20, Fig. 5) including various external input devices that receive commands from the patient, which are communicated to the control element (50, Fig. 5) through the main CPU (22, Fig. 4) for the administering of medication "upon demand" (see: Kaufman et al.: column 8, lines

30-37). In addition, the medication control element (50, Fig. 5) can store and selectively administer medication upon demand by patient (see: Kaufman et al.: column 9, lines 17-25). Furthermore, Kraft et al. and Kaufman et al. teach that a plurality of dispensers are networked together and connected to a common database of patient information, typically a pharmacy software system. Medications are automatically dispensed responsive to a user request in accordance with the information in the database and the dispensers communicates data for accounting and billing purposes (reads on "charging an account"), to the pharmacy system or to another system (see: Kraft et al.: column 2, lines 22-29).

Kraft et al. and Kaufman et al. fail to teach at least one input device includes a card reader device, wherein the card reader device is in operative connection with the computer, and further comprising:

(g) reading a credit or debit card with the card reader device, and charging an account associated with the credit or debit card.

Cummings, Jr. teaches a fully integrated and comprehensive health care system with a terminal that includes a main housing (50, Fig. 2) having a visual display window (51, Fig. 2) and a card data entry slot (52, Fig. 2) used for inserting a conventional or special data-containing card (e.g., a swipe card) into the entry slot and moving it laterally (see: column 7, lines 17-37).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the fully integrated and comprehensive health care system with card entry slot (52, Fig. 2) as taught by Cummings, Jr. with the system of Kraft et al. and Kaufman et al. with motivation of providing a reliable and simple method of payment for a patient health care.

As per claim 33, Kraft et al. and Kaufman et al. teach system (20, Fig. 5) including various external input devices that receive commands from the patient, which are communicated to the control element (50, Fig. 5) through the main CPU (22, Fig. 4) for the administering of medication "upon demand" (see: Kaufman et al.: column 8, lines 30-37). In addition, the medication control element (50, Fig. 5) can store and selectively administer medication upon demand by patient (see: Kaufman et al.: column 9, lines 17-25). Furthermore, Kraft et al. and Kaufman et al. teach that a plurality of dispensers are networked together and connected to a common database of patient information, typically a pharmacy software system. Medications are automatically dispensed responsive to a user request in accordance with the information in the database and the dispensers communicates data for accounting and billing purposes (reads on "payment"), to the pharmacy system or to another system (see: Kraft et al.: column 2, lines 22-29).

Kraft et al. and Kaufman et al. fail to teach the payment comprises a co-payment, wherein (f) includes receiving the co-payment from the patient corresponding to the at least one medical item requested in the dispense request input.

Cummings, Jr. teaches a fully integrated and comprehensive health care system with a terminal that includes a main housing (50, Fig. 2) having a visual display window (51, Fig. 2) and a card data entry slot (52, Fig. 2) used for inserting a conventional or special data-containing card (e.g., a swipe card) into the entry slot and moving it laterally (see: column 7, lines 17-37). Cummings, Jr. further teaches after a card is swiped (101, Fig. 5) and the charges to the patient are in agreement the System processor calculates any patient co-pay and/or deductible (140, Fig. 6) and payment is transmitted to provider account (204, Fig. 8) (see: column 12, lines 22-32 and column 13, lines 41-58).

The obviousness of combining the teachings of Cummings, Jr. with the system of Kraft et al. and Kaufman et al. is discussed in the rejection of claim 32, and incorporated herein.

As per claims 40-41, they are rejected for the same reasons set forth in claims 33 and 32, respectively.

As per claim 45, Kraft teaches a method comprising

(a) storing in at least one data store in operative connection with at least one computer, data representative of each of:

a plurality of types of medical items,

the type of medical item stored in each respective storage location,

at least one patient, and

at least one medical item type prescribed for use by the at least one patient is met by storing information concerning a patient's medication requirements on the pharmacy system (14, Fig. 1) that maintains a database of the medication, the manufacturer, the brand name, the generic name, the dosage form, the location of the drug in the pharmacy, and pricing information (see: column 1, lines 29-34 and column 4, lines 56-59);

(g) dispensing from the dispenser apparatus to the patient the requested at least one medical item type, wherein the at least one medical item type is dispensed from at least one storage location holding the at least one medical item type is met by the dispensing process where the nurse enter commands through the system controller (34, Fig. 3) to retrieve medication for one or more patients (see: column 4, lines 54-56);

(h) verifying with the dispenser apparatus that the requested at least one medical item type was dispensed to the patient, including at least one sensor in the dispenser apparatus transmitting at least one signal to the computer responsive to the at least one

sensor sensing a passing of the requested at least one medical item type is met by the vision subsystem (44, Fig. 4) comprises two optic systems for comparing specific medication in order to verify that the correct medication is being dispensed (see: column 7, lines 26-34); and

(i) including in the at least one data store responsive to (h), data linking each of the patient, the verified dispensed at least one medical item type, and location of the dispensing of the verified dispensed at least one medical item type is met by the vision subsystem (44, Fig. 4) comprises two optic systems for comparing specific medication in order to verify that the correct medication is being dispensed (see: column 7, lines 26-34).

Furthermore, Kraft et al. teach that a plurality of dispensers are networked together and connected to a common database of patient information, typically a pharmacy software system. Medications are automatically dispensed responsive to a user request in accordance with the information in the database and the dispensers communicates data for accounting and billing purposes (reads on "(e) charging an amount to an account, wherein the amount corresponds to a payment associated with the requested at least one medical item type"), to the pharmacy system or to another system (see: column 2, lines 22-29).

Kraft et al. fails to teach:

dispensing to the patient;

a plurality of medical item in a patient-accessible self service medical item dispenser apparatus;

(b) receiving patient identification data from a patient through at least one input device of the dispenser apparatus;

(c) receiving from the patient through the at least one input device a request to dispense at least one medical item type prescribed for use by the patient; and

(f) instructing the dispenser apparatus to dispense to the patient the requested at least one medical item type.

Kaufman et al. teaches an interactive patient assistance and delivery system that includes a system (200, Fig. 11) for storing and delivering of individual pills or caplets as well as both external and internal devices (55, Fig. 5) for receiving input from the physician (or healthcare professional at the central monitoring facility 28, Fig. 4a), the individual patient, the physical testing devices (34, Fig. 4a) and (36, Fig. 4a) and the environmental sensors (23, Fig. 8a) and (25, Fig. 8a) in order to gain access to the medication delivery system (20, Fig. 5) (see: column 8, lines 15-23, column 17, lines 1-22 and Fig. 11-13). In addition, Kaufman teaches a medication control element (50, Fig. 5) that can store and selectively administer medication upon demand by patient (see: column 9, lines 17-25).

The obviousness of combining the teachings of Kaufman et al. within the system as taught by Kraft et al. is discussed in the rejection of claim 28, and incorporated herein.

Kraft et al. and Kaufman fail to teach:

(d) reading a credit or debit card with a card reader device of the dispenser apparatus;

Cummings, Jr. teaches a fully integrated and comprehensive health care system with a terminal that includes a main housing (50, Fig. 2) having a visual display window (51, Fig. 2) and a card data entry slot (52, Fig. 2) used for inserting a conventional or

special data-containing card (e.g., a swipe card) into the entry slot and moving it laterally (see: column 7, lines 17-37).

The obviousness of combining the teachings of Cummings, Jr. with the system of Kraft et al. and Kaufman et al. is discussed in the rejection of claim 32, and incorporated herein.

Response to Arguments

9. Applicant's arguments filed 3/1/03 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 3/1/03.

(A) In the remarks, Applicants argues in substance that (1) Kraft does not teach the storing in a data store that a medical item has been dispensed responsive to execution of the dispensing of the medical item from the dispenser for use by the patient; and (2) the Liff reference cannot constitute prior art pursuant to 35 USC § 103(a) because Liff has a filing date of May 3, 1996 and claims priority as a continuation-in-part of U.S. Patent 5,713,485 filed October 18, 1995 and the present invention is entitled to earlier priority, including at least the December 16, 1994 filing date of U.S. Patent No. 5,790,409.

(B) In response to the Applicant's arguments, (1) Kraft does not teach the storing in a data store that a medical item has been dispensed responsive to execution of the dispensing of the medical item from the dispenser for use by the patient. The Examiner respectfully submits that Kraft et al. teaches a pharmacy computer system that maintains a database of the medication, the manufacturer, the brand name, the generic name, the dosage form, the location of the drug in the pharmacy, and pricing information (see:

column 1, lines 29-34). In addition, Kraft et al. teaches a system controller (34, Fig. 2) that communicates accounting information so that the patients are accurately billed as medications are dispensed. The information on the quantity and type of medication dispensed for each patient is communicated to the pharmacy system (or other accounting system) and information regarding the time of dispensing and the type and quantity of medication dispensed can be used to ensure that the medication was properly administered (see: column 5, lines 47-55). This clearly discloses that a database is used to store information regarding the type of medical item in the dispenser and the system controller communicates information regarding the time, quantity and type of medication being dispensed and used by each patient.

(C) In response to the Applicant's arguments, (2) the Liff reference cannot constitute prior art pursuant to 35 USC § 103(a) because Liff has a filing date of May 3, 1996 and claims priority as a continuation-in-part of U.S. Patent 5,713,485 filed October 18, 1995 and the present invention is entitled to earlier priority, including at least the December 16, 1994 filing date of U.S. Patent No. 5,790,409 (hereinafter "Fedor"). The Examiner respectfully submits that Liff was only relied on for the data representative of a benefit plan associated with the patient, and payment rules concerning payment for medical items associated with the benefit plan and the step of charging for the dispensed medical item in accordance with the payment rules. The reference of Fedor does not cite or mention a benefit plan or payment rules associated with a benefit plan and Liff reference is used to reject this particular limitation only, therefore the use of the Liff reference is proper and maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (703) 605-4441. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7687 for regular communications and (703) 305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

RWM
rwm
June 1, 2003

JOSEPH THOMAS
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TECHNOLOGY CENTER 3600